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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,492	04/08/2004	David J. Bayer	04819-15	7284

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EXAMINER
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NATNITHADHA, NAVIN

ART UNIT	PAPER NUMBER
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3735

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06/25/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/820,492	<b>Applicant(s)</b> BAYER ET AL.	
	<b>Examiner</b> NAVIN NATNITHITHADHA	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,8-13,15,16,23-29,31-39,41-54 and 57-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8-13,15,16,23-29,31-39,41-54 and 57-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06 April 2009 has been entered.

### ***Response to Amendment***

2. According to the Amendment, filed 06 April 2009, the status of the claims is as follows:

Claims 1, 4-6, 8, 12, 13, 15, 23, 26-29, 31, 35, 36, 41-47, 50, 52, 54, 57, 59, and 61 are currently amended;

Claims 9-11, 16, 24, 32-34, 37-39, 48, 49, 51, 53, 58, and 60 are as originally filed;

Claims 25 are previously presented; and

Claims 7, 14, 17-22, 30, 40, 55, and 56 are cancelled.

***Response to Arguments***

3. Applicant's arguments, see Remarks, pp. 12-14, filed 06 April 2009, with respect to the rejection of claims 1, 4-6, 8-10, and 12 under 35 U.S.C. 103(a) as being Mault et al, U.S. Patent No. 6,468,222 B1 ("Mault"), in view of Sheehan et al, U.S. Patent No. 6,319,199 B1 ("Sheehan"), Raemer et al, U.S. Patent No. 4,233,842 A ("Raemer"), and Burroughs, U.S. Patent No. 3,880,591 A ("Burroughs"), have been fully considered, but they are not persuasive.

As to claim 1, Applicant contends, see Remarks, p. 13, the following:

Claim 1 is patentable over U.S. Patent No. 6,468,222 to Mault et al. (hereinafter referred to as "Mault") in view of U.S. Patent No. 6,319,199 to Sheehan et al. ("Sheehan"), U.S. Patent No. 4,233,842 to Raemer et al. ("Raemer"), and U.S. Patent No. 3,880,591 to Burroughs ("Burroughs") in that, whether considered alone or in combination, these references fail to teach or suggest a breath testing device housing that includes 1) a display oriented on *the front edge* of the base, 2) a manual sample button located on *the back edge* of said base opposite the display, and 3) a mouthpiece interface comprising a *generally U-shaped channel* sized to receive a mouthpiece therein, the mouthpiece being configured to be pivotally coupled with respect to the mouthpiece interface.

However, this argument is not persuasive.

Firstly, the phrase "front edge" is an arbitrary description. Thus, Mault's "front cap 74", where the display 18 is located, can reasonably be interpreted as being a "front edge".

Secondly, Sheehan teaches a "manual sample button" 218 located on the "back edge" of the "base" 209. Thus, it would have been obvious to one of ordinary skill in the art to have the manual sample button located on the back edge of the base because the

modification would provide predictable results. Moreover, Applicant has not provided reasons why this modification provides an advantage over Mault's design.

Thirdly, Mault teaches a mouthpiece interface 26 comprising a generally U-shaped channel sized to receive a mouthpiece therein (see fig. 3). Moreover, the mouthpiece 34 being configured to be pivotally coupled with respect to the mouthpiece interface 26 because the insertion of the mouthpiece 34 requires inserting one side of the mouthpiece 34 and then pivoting the mouthpiece 34 in order for the other side of the mouthpiece 34 is inserted.

4. In the Remarks, filed 06 April 2009, Applicant did not submit arguments with respect to the rejection of claim 11 under 35 U.S.C. 103(a) as being Mault in view of Sheehan, Raemer, and Burroughs, as applied to claim 1 above, and further in view of Wolf, U.S. Patent No. 5,291,898 A ("Wolf"). Therefore, the rejection of claim 11 is maintained. Applicant mentions claim 11 in the Remarks, p. 15, filed 06 April 2009. However, the discussion, directed to claim 11, clearly discusses subject matter of claim 13 and not claim 11. It appears "claim 11" was a typographical error.

5. Applicant's arguments, see Remarks, pp. 14-15, filed 06 April 2009, with respect to the rejection of claims 13, 15, and 16 under 35 U.S.C. 103(a) as being Lutz et al , U.S. Patent No. 4,274,425 A ("Lutz") in view of Mault, have been fully considered, but they are not persuasive.

As to claim 13, Applicant contends, see Remarks, p. 15, the following:

More specifically, neither Lutz nor Mault, considered alone or in combination, describes or suggests a mouthpiece that includes a discard breath outlet oriented such that discard breath is not directed into the device or at an operator of the breath testing device during testing.

However, this argument is not persuasive. Since the limitation contains alternative language, Mault teaches a mouthpiece 34 that includes a discard breath outlet 36 oriented such that discard breath is not directed at an operator of the breath testing device 10 during testing.

6. Applicant's arguments, see Remarks, pp. 15-16, filed 06 April 2009, with respect to the rejection of claims 23, 24, 26-29, 31, 32, 34, 47, 48, and 50-53 under 35 U.S.C. 103(a) as being Mault in view of Raemer, have been fully considered, but they are not persuasive.

As to claim 23, Applicant contends, see Remarks, p. 15, the following:

More specifically, neither Mault nor Raemer teaches or suggests a breath tester housing assembly that includes a mouthpiece configured to be removably coupled to said mouthpiece interface, said mouthpiece comprising an elongate body comprising at least one substantially planar surface, an opened end, and a closed end, the closed end and substantially planar surface of the mouthpiece being placed against the mouthpiece interface in a testing position.

However, this argument is not persuasive. Mault teaches a breath tester housing assembly 10 that includes a mouthpiece 34 configured to be removably coupled to said mouthpiece interface 26, said mouthpiece 34 comprising an elongate body 34 comprising at least one substantially planar surface 28, an opened end 32, and a closed end 40, the closed end 40 and substantially planar surface 28 of the mouthpiece 34 being placed against the mouthpiece interface 26 in a testing position (see fig 4).

7. Applicant's arguments, see Remarks, pp. 18-20, filed 06 April 2009, with respect to the rejection of claims 36-42, 44, 45, and 61 under 35 U.S.C. 103(a) as being Mault

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in view of Raemer and Brown et al, U.S. Patent No. 5,303,575 A ("Brown"), have been fully considered, but they are not persuasive.

As to claim 61, Applicant contends, see Remarks, p. 18, the following:

More specifically, neither Mault nor Raemer describes or suggests a breath testing device housing that includes 1) a display oriented on the front edge (as explained above with respect to Claim 1) or 2) a mouthpiece being configured to pivotally couple with the mouthpiece interface (as explained above with respect to Claim 47).

However, this argument is not persuasive for the same reasons as explained above for claims 1 and 47.

As to claim 36, Applicant contends, see Remarks, p. 19, the following:

Claim 36 is patentable over Mault in view of Raemer and U.S. Patent No. 5,303,575 to Brown et al. (hereinafter referred to as "Brown") in that neither Mault, Raemer nor Brown, whether considered alone or in combination, teach or suggest a breath tester housing assembly that includes a mouthpiece configured to be removably coupled to the housing and extend obliquely from the housing and wherein the mouthpiece is configured to be pivotally coupled to the housing.

However, this argument is not persuasive. Firstly, Mault teaches a breath tester housing assembly 10 that includes a mouthpiece 34 configured to be removably coupled to the housing 10. Secondly, Brown does, in fact, teach the straw extends obliquely from the housing (see fig. 1). In addition, Applicant has not provided any reasons why this feature is novel or obvious over either Brown or Mault's design.

8. In the Remarks, filed 06, April 2009, Applicant did not submit arguments with respect to the rejection of claim 25 under 35 U.S.C. 103(a) as being Mault in view of Raemer, as applied to claim 24 above, and further in view of Sheehan. Therefore, the rejection of claim 25 is maintained.

9. In the Remarks, filed 06, April 2009, Applicant did not submit arguments with respect to the rejection of claim 43 under 35 U.S.C. 103(a) as being Mault in view of Raemer and Brown, as applied to claim 37 above, and further in view of Sheehan. Therefore, the rejection of claim 43 is maintained.

10. In the Remarks, filed 06, April 2009, Applicant did not submit arguments with respect to the rejection of claim 33 under 35 U.S.C. 103(a) as being Mault in view of Raemer, as applied to claim 23 above, and further in view of Wolf. Therefore, the rejection of claim 33 is maintained.

11. In the Remarks, filed 06, April 2009, Applicant did not submit arguments with respect to the rejection of claims 35 and 49 under 35 U.S.C. 103(a) as being Mault in view of Raemer, as applied to claims 23 and 47 above, and further in view of Lutz. Therefore, the rejection of claims 35 and 49 is maintained.

12. In the Remarks, filed 06, April 2009, Applicant did not submit arguments with respect to the rejection of claim 46 under 35 U.S.C. 103(a) as being Mault in view of Raemer and Brown, as applied to claim 37 above, and further in view of Lutz. Therefore, the rejection of claim 46 is maintained.

13. Applicant's arguments, see Remarks, pp. 20-21, filed 06 April 2009, with respect to the rejection of claims 54, 55, and 57-60 under 35 U.S.C. 103(a) as being Mault in view of Lutz, have been fully considered, but they are not persuasive.

As to claim 54, Applicant contends, see Remarks, p. 20, the following:

More specifically, neither Mault nor Lutz teaches or suggests a mouthpiece that includes at least one port being oriented such that discard breath is not directed towards an operator of the breath testing device during testing. See Applicants' remarks with respect to claim 13.



However, this argument is not persuasive for the same reasons as explained above for claim 13.

14. Applicant's arguments, see Remarks, p. 21, filed 06 April 2009, with respect to the rejection of claims 13, 15, 16, 23-27, 47-55, and 57-61 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 11-29 of U.S. Patent Application No. 11/089,655, have been fully considered. The rejection is withdrawn because U.S. Patent Application No. 11/089,655 has been abandoned thereby rendering this rejection moot.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1, 4-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Sheehan, Raemer, and Burroughs, U.S. Patent No. 3,880,591 A ("Burroughs").

In reference to claims 1, 7, 9 and 12:

Mault teaches:

A calorimeter for measuring the metabolic rate of a subject, which comprises a symmetrical housing and base (12 of Mault) to be

gripped by an operator, which has a front edge (the same side display 18 of Mault) and an opposite back edge (the same side as mouthpiece 14). The device further comprises a display (18 of Mault) oriented on one of the edges and aligned with an operator's direct line of view while gripping the base (Fig. 1 of Mault). A mouthpiece interface (32 of Mault) is used for interfacing with a removable mouthpiece, wherein the mouthpiece interface is oriented with respect to the base such that when the operator stands in front of the subject and a subject blows into the mouthpiece the display is not in the direct line of view of the subject (Fig. 1 of Mault). An actuator including a manual sample button (16 of Mault) is located on the edge adjacent to the display. The discard breath is not directed at the operator (port G, and 72 of Mault).

However, Mault fails to teach that:

The actuator is located on the edge of the base opposite the display and an alcohol sensor is fluidly connected to the mouthpiece interface. The alcohol sensor being adapted to detect alcohol present in the subject by the subject blowing into the mouthpiece.

Sheehan teaches:

A portable data collection device for diagnosing and data collection (Abstract of Sheehan) comprising actuator buttons placed on the

same (216 of Sheehan) or opposite (218 of Sheehan) side of the display (220 of Sheehan). The input dials (216 and 218 of Sheehan) control the operation of the device.

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have placed the operating actuator buttons on the gripping handle of the device, similar to the teachings of Sheehan, in the Calorimeter of Mault, in order to allow the subject more convenience while operating the device.

However, the combination fails to teach that:

An alcohol sensor is fluidly connected to the mouthpiece interface, the alcohol sensor being adapted to detect alcohol present in the subject by the subject blowing into the mouthpiece.

Raemer teaches:

An apparatus used for detection and measurement of selected fluids in expired air taken from a living individual (Fig. 1 of Raemer) which comprises a sensors (22 and 13 of Raemer). The system is capable of detecting different respiratory fluids based on the measurement of CO<sub>2</sub> and O<sub>2</sub> levels, such as the metabolic rate of the subject or anesthetic vapors or blood alcohol of the user (Col. 5, lines 13-28 and Col. 6, lines 41-58 of Raemer).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the

metabolic calorimeter of Mault as modified by Sheehan to be able to measure other expiratory fluids, such as blood alcohol or anesthetic vapors, as taught by Raemer in order to be able to detect and measure different types of fluid in the exhaled breath of an individual.

However, the combination fails to teach that:

The mouthpiece interface comprises a channel sized to receive the mouthpiece therein, the mouthpiece configured to be pivotally coupled in one orientation within the mouthpiece interface.

Burroughs teaches:

A breath testing device 12 (Figs. 1-3 of Burroughs), comprising: a mouthpiece interface for interfacing with a removable mouthpiece 14, the mouthpiece interface comprising a channel 16 sized to receive the mouthpiece 14 therein, the mouthpiece 14 configured to be pivotally coupled in one orientation within the mouthpiece interface (see Col. 4, lines 12-26, of Burroughs).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the metabolic calorimeter of Mault to have a mouthpiece interface comprising a channel sized to receive the mouthpiece therein and the mouthpiece configured to be pivotally coupled in one orientation within the mouthpiece interface because Burroughs teaches such a mouthpiece interface design that could be used with a "wide variety of devices, instruments and

systems which are constructed to receive breath expelled by a subject individual and to provide useful information derived from a sample of such breath or from the act of expiring or exhaling" (see Col. 1, lines 4-19, and Col. 3, lines 5-13, of Burroughs).

In reference to claim 4:

The housing assembly comprises a first sidewall (the side towards 74 of Mault) and an opposite second sidewall (26 of Mault) coupled together at a front edge (the edge towards element 34 of Mault) and a back edge (the connection edge on the opposite side). The first and second sidewalls are extended radially between a top surface (the side towards 68 of Mault) and a bottom surface (the side towards 70 of Mault). The display is located along the front edge, and the mouthpiece interface is located along the top surface (Figs. 3 and 4 of Mault).

In reference to claims 5 and 6:

The mouthpiece interface is oriented with respect to the housing such that the mouthpiece extends outward from the housing back edge when the mouthpiece is coupled to the housing (Fig. 2 of Mault). The mouthpiece extends obliquely from the top surface and substantially parallel to the top surface (Figs. 21 and 24 of Mault).

The mouthpiece of Mault does not extend obliquely from the top surface and as disclosed in Figs. 2 and 4 it extends directly (perpendicular to the top surface) from the top surface of the housing. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of

ordinary skill in the art to have placed the mouthpiece of Mault in an oblique position rather than a perpendicular position. Applicant has not disclosed that positioning the mouthpiece in a particular angle provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece positioned at an oblique or perpendicular angle. Therefore it would have been obvious to modify Mault to obtain the invention as specified in claims 5 and 6 because such modifications would have been considered a mere design choice which fails to patentably distinguish over the prior art of Mault.

In reference to claims 8 and 10:

An actuator (16 of Mault) is used for controlling illumination of a portion of the housing. A light source illuminates at least a portion of the interface, where the housing has an opening for light to pass from an interior of the housing to an exterior of the housing for illuminating at least a portion of the interface (Col. 3, line 59- Col. 4, line 5 of Mault).

16. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Sheehan, Raemer, and Burroughs, as applied to claim 1 above, and further in view of Wolf.

In reference to claim 11:

Mault, as modified by Sheehan and Raemer, teaches all of the claim limitations;

See the rejection of claim 1 above.

However, the combination fails to teach that:

The housing comprises a mouthpiece ejector for facilitating removal of the mouthpiece from the housing.

Wolf teaches:

A hand held device for measuring breath alcohol which comprises an ejector (120 of Wolf) for ejecting the mouthpiece forceably so that the mouthpiece is ejected into a refuse container or onto the ground without the need of the officer administering the test to touch the used mouthpiece (Col. 9, lines 9-17 of Wolf).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have added an ejector, similar to the one taught by Wolf, in the calorimeter level measurement device of Mault, as modified by Sheehan and Raemer, in order to prevent the operator from touching the used mouthpiece after it has been used by the subject.

17. Claims 13 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,274,425 to Lutz et al (Hereinafter "Lutz") in view of Mault.

In reference to claims 13 and 15-16:

Lutz teaches:

A device for measuring redox gases, such as alcohol, in a person's breath, which comprises a disposable mouthpiece (Abstract of

Lutz). The mouthpiece (5 of Lutz) comprises a first end (39 of Lutz) and a second end (27 of Lutz). The second end is closed and is rounded to facilitate engagement with the breath testing device (Fig. 1 of Lutz). The mouthpiece further comprises at least one port for channeling air blown into the mouthpiece (through 39 and 15 of Lutz) into the breath testing device. The mouthpiece is made of plastic material (Col. 1, lines 48-50 of Lutz). The mouthpiece snaps into engagement with the breath testing device (snap members 23, 25, 33 and 35 and Col. 3, lines 40-52 of Lutz). A stop member (the bend at 41 of Lutz) extending radially outward from the body to facilitate positioning a subject's mouth during breath testing (Fig. 1 of Lutz).

However, Lutz fails to teach that:

The mouthpiece has a cross-sectional shape being one of: a D-shaped cross-sectional shape and a V-shaped cross-sectional shape.

Mault teaches:

A calorimeter used for measuring the metabolic rate of a subject which comprises a symmetrical housing and base (12 of Mault) to be gripped by an operator (the same side display 18 of Mault). The housing further comprises a mouthpiece interface sized to receive a mouthpiece in sealing contact therein (the inlet port 346 of Mault



creates an airtight seal). A portion of the mouthpiece body has a selected cross-sectional shape being one of a D-shaped cross-sectional shape or a V-shaped cross-sectional shape (Fig. 23 of Mault discloses a D-shape cross-section).

The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used a different design for the mouthpiece of Mault such as a mouthpiece with a V-shape cross-section rather than a D-shape cross-section. Applicant has not disclosed that choosing a V-shape cross-section for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs.

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have replaced the mouthpiece of Lutz with a mouthpiece similar to the one taught by Mault in order to collect breath samples from the subject for further analysis. Substituting one known element with another would have yielded predictable results. It would have been obvious to modify Mault to obtain

the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentable distinguish over the prior art of Mault.

18. Claims 23-24, 26-32, 34, 47-48, 50-53, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer.

In reference to claims 23-24 and 29-30:

Mault teaches:

A calorimeter for measuring the metabolic rate of a subject which comprises housing (10 of Mault), which comprises a base (12 of Mault), a display (18 of Mault), and a mouthpiece interface (14 or 20 of Mault). The base can be gripped by an operator during testing, and the display is oriented with respect to the housing to be in line with an operator's direct line of view while gripping the base (Fig. 1 of Mault). The mouthpiece is removably coupled to the mouthpiece interface (346 in Fig. 23 and 326 in Fig. 21 of Mault). The mouthpiece comprises at least one substantially planar surface (Fig. 23 of Mault). The mouthpiece interface includes a stop for positively locating the mouthpiece (the ring around the connection 332 of Mault). The mouthpiece is placed against the stop in a testing position (Fig. 21 of Mault). The housing further comprises at least one actuator for controlling operation of the breath tester (16

of Mault). The mouthpiece is further oriented with respect to the housing such that discard breath discharged from the housing is not directed at the operator (Fig. 4 and output port G, or 72 of Mault).

However, Mault fails to teach that:

An alcohol sensor is fluidly connected to the mouthpiece interface, the alcohol sensor being adapted to detect alcohol present in the subject by the subject blowing into the mouthpiece.

Raemer teaches:

An apparatus used for detection and measurement of selected fluids in expired air taken from a living individual (Fig. 1 of Raemer) which comprises sensors (22 and 13 of Raemer). The system is capable of detecting different respiratory fluids based on the measurement of CO<sub>2</sub> and O<sub>2</sub> levels, such as the metabolic rate of the subject or anesthetic vapors or blood alcohol of the user (Col. 5, lines 13-28 and Col. 6, lines 41-58 of Raemer).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the metabolic calorimeter of Mault to be able to measure other expiratory fluids, such as blood alcohol or anesthetic vapors, as taught by Raemer in order to be able to detect and measure different types of fluid in the exhaled breath of an individual.

In reference to claims 26-28:

The housing assembly comprises a first sidewall (the side towards 74 of Mault) and an opposite second sidewall (26) coupled together at a front edge (the edge towards element 34 of Mault) and a back edge (the connection edge on the opposite side). The first and second sidewalls are extended radially between a top surface (the side towards 68) and a bottom surface (the side towards 70 of Mault). The display is located along the front edge, and the mouthpiece interface is located along the top surface (Figs. 3 and 4 of Mault). The mouthpiece interface is further oriented obliquely from the top surface and is substantially parallel to the top surface (Figs. 21 and 23 of Mault). The housing further comprises a mouthpiece interface sized to receive a mouthpiece in sealing contact therein (the inlet port 346 of Mault creates an airtight seal). The mouthpiece comprises one of a tube and a funnel (Fig. 23 of Mault).

The mouthpiece of Mault does not extend obliquely from the top surface and as disclosed in Figs. 2 and 4 it extends directly (perpendicular to the top surface) from the top surface of the housing. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have placed the mouthpiece of Mault in an oblique position rather than a perpendicular position. Applicant has not disclosed that positioning the mouthpiece in a particular angle provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform

equally well with either mouthpiece positioned at an oblique or perpendicular angle. Therefore it would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentably distinguish over the prior art of Mault.

In reference to claims 31-32:

The housing comprises one actuator (16) for controlling illumination of a portion of the housing. A light source is used for illuminating at least a portion of the interface, where an opening on the housing will pass light from an interior to an exterior of the housing (Col. 3, line 59-Col. 4, line 5 of Mault).

In reference to claim 34:

A portion of the body has a selected cross-sectional shape being one of a D-shaped cross-sectional shape and a V-shaped cross-sectional shape (Fig. 23 of Mault discloses a D-shape cross-section).

The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used a different design for the mouthpiece of Mault such as a mouthpiece with a V-shape cross-section rather than a D-shape cross-section. Applicant has not disclosed that choosing a V-shape cross-section for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected

Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs. It would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentably distinguish over the prior art of Mault.

In reference to claim 47:

Mault teaches a calorimeter for measuring the metabolic rate of a subject, which comprises a mouthpiece (14 or 20 of Mault). The mouthpiece comprises a first end (seal 354 of Mault), a second end (the end attached to 346 of Mault), and a body extending there between (344 of Mault). A portion of the body has a selected cross-sectional shape being one of a D-shaped cross-sectional shape and a V-shaped cross-sectional shape (Fig. 23 of Mault discloses a D-shape cross-section. The body further comprises a passageway extending through the body from the first end towards the second end (Fig. 24 of Mault), where the passageway channels the air blown into the mouthpiece into the breath testing device (Fig. 4 of Mault).

The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used a different design for the mouthpiece of Mault such as a mouthpiece with a V-shape cross-section rather than a D-shape

cross-section. Applicant has not disclosed that choosing a V-shape cross-section for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs. It would have been obvious to modify Mault to obtain the invention as specified in claim 47 because such modifications would have been considered a mere design choice which fails to patentably distinguish over the prior art of Mault.

In reference to claims 48 and 50-53:

The body further comprises an external surface (the outside surface of 344 of Mault), an internal surface (internal surface of 344 of Mault), and at least one inlet port (30 of Mault) extending there between. The inlet port channels air from the passageway into the breath testing device (Fig. 4 of Mault). The mouthpiece comprises a substantially planar surface (Fig. 24 of Mault). One of the first end and the second end is rounded to facilitate engagement with the breath testing device (the connection 346 of Mault to the second end of the mouthpiece).

19. Claims 36-42, 44, 45, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer and Brown et al, U.S. Patent No. 5,303,575 A ("Brown").

In reference to claims 36-37 and 40-42, and 61:

Mault teaches:

A calorimeter used for measuring the metabolic rate of a subject which comprises a symmetrical housing and base (12 of Mault) to be gripped by an operator, which has a front edge (the same side display 18 of Mault) and an opposite back edge (the same side as mouthpiece 14). The device further comprises a display (18 of Mault) oriented on one of the edges and aligned with an operator's direct line of view while gripping the base (Fig. 1 of Mault). A mouthpiece interface (32 of Mault) is used for interfacing with a removable mouthpiece (326 of Mault), wherein the mouthpiece interface is oriented with respect to the base such that when the operator stands in front of the subject and a subject blows into the mouthpiece the display is not in the direct line of view of the subject (Fig. 1 of Mault). The housing assembly comprises a first sidewall (the side towards 74 of Mault) and an opposite second sidewall (26) coupled together at a front edge (the edge towards element 34 of Mault) and a back edge (the connection edge on the opposite side). The first and second sidewalls are extended radially between a top surface (the side towards 68) and a bottom surface (the side towards 70 of Mault). The display is located along the front edge, and the mouthpiece interface is located along the top surface (Figs. 3 and 4 of Mault). The mouthpiece interface is further oriented obliquely from the top surface and is substantially parallel to the top



surface (Figs. 21 and 23 of Mault). The housing further comprises a mouthpiece interface sized to receive a mouthpiece in sealing contact therein (the inlet port 346 of Mault creates an airtight seal). The mouthpiece comprises one of a tube and a funnel (Fig. 23 of Mault).

As to added limitation, Mault teaches that:

The mouthpiece 326 further configured to be pivotally coupled in one orientation within the housing 320 (Figs. 21 and 22 of Mault).

However, Mault teaches that:

The mouthpiece does not extend obliquely from the housing and as disclosed in Figs. 2 and 4 it extends directly perpendicular from the housing.

Brown teaches:

A breath tester assembly 20 comprising a mouthpiece 24 that extends obliquely from a housing 21. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have placed the mouthpiece of Mault in an oblique position rather than a perpendicular position. Applicant has not disclosed that positioning the mouthpiece in a particular angle provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece

and Applicant's invention to perform equally well with either mouthpiece positioned at an oblique or perpendicular angle.

Therefore it would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentable distinguish over the prior art of Mault.

However, Mault fails to teach that;

An alcohol sensor is fluidly connected to the mouthpiece interface, the alcohol sensor being adapted to detect alcohol present in the subject by the subject blowing into the mouthpiece.

Raemer teaches:

An apparatus used for detection and measurement of selected fluids in expired air taken from a living individual (Fig. 1 of Raemer), which comprises a sensors (22 and 13 of Raemer). The system is capable of detecting different respiratory fluids based on the measurement of CO<sub>2</sub> and O<sub>2</sub> levels, such as the metabolic rate of the subject or anesthetic vapors or blood alcohol of the user (Col. 5, lines 13-28 and Col. 6, lines 41-58 of Raemer).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the metabolic calorimeter of Mault to be able to measure other expiratory fluids, such as blood alcohol or anesthetic vapors, as taught

by Raemer in order to be able to detect and measure different types of fluid in the exhaled breath of an individual.

In reference to claims 38-39:

The housing comprises one actuator (16) for controlling illumination of a portion of the housing. A light source is used for illuminating at least a portion of the interface, where an opening on the housing will pass light from an interior to an exterior of the housing (Col. 3, line 59-Col. 4, line 5 of Mault).

In reference to claim 44:

A portion of the mouthpiece has a cross-sectional shape that is substantially similar to at least portion of a cross-sectional shape defined by the mouthpiece interface, such that the mouthpiece interface facilitates positioning the mouthpiece in proper alignment with respect to the housing (the inlet port 346 of Mault and the narrower side of the funnel 344 of Mault have the same cross section).

In reference to claim 45:

A portion of the body has a selected cross-sectional shape being one of a D-shaped cross-sectional shape and a V-shaped cross-sectional shape (Fig. 23 of Mault discloses a D-shape cross-section).

The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used a different design for the mouthpiece of

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Mault such as a mouthpiece with a V-shape cross-section rather than a D-shape cross-section. Applicant has not disclosed that choosing a V-shape cross-section for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs. It would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentably distinguish over the prior art of Mault.

20. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer, as applied to claim 24 above, and further in view of Sheehan; and Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer and Brown, as applied to claim 37 above, and further in view of Sheehan.

In reference to claims 25 and 43:

Mault, as modified by Raemer, or Raemer and Brown, teaches all of the claim limitations; see the rejections of claim 23 and 37 above.

However the combination fails to teach that:

The manual sample button is located on an edge of the housing base that is opposite an edge where the display is located.

Sheehan teaches:

A portable data collection device for diagnosing and data collection

(Abstract of Sheehan) comprising actuator buttons placed on the same (216 of Sheehan) or opposite (218 of Sheehan) sides of the display (220 of Sheehan). The input dials (216 and 218 of Sheehan) control the operation of the device.

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have placed the operating actuator buttons on the gripping handle of the device, similar to the teachings of Sheehan, in the Calorimeter of Mault as modified by Raemer, in order to give the subject more convenience while operating the device.

21. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer as applied to claim 23 above, and further in view of Wolf.

In reference to claim 33:

Mault, as modified by Reamer teaches all of the claim limitations; see the rejection of claim 23 above.

However, the combination fails to teach that:

The housing comprises a mouthpiece ejector for facilitating removal of the mouthpiece from the housing.

Wolf teaches:

A hand held device for measuring breath alcohol which comprises an ejector (120 of Wolf) for ejecting the mouthpiece forceably, so

that the mouthpiece is ejected into a refuse container or onto the ground without the need of the officer administering the test to touch the used mouthpiece (Col. 9, lines 9-17 of Wolf).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have added an ejector, similar to the one taught by Wolf, in the calorimeter level measurement device of Mault as modified by Raemer in order to prevent the operator from touching the used mouthpiece after it has been used by the subject.

22. Claims 35 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer as applied to claims 23 and 47 above, and further in view of Lutz; and Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer and Brown, as applied to claim 37 above, and further in view of Lutz.

In reference to claims 35 and 46:

Mault, as modified by Raemer, or Raemer and Brown, teaches all of the claim limitations; see the rejections of claim 23 and 37 above.

However, the combination fails to teach that:

The first end of the mouthpiece body is closed and an opposed second end of the body is open to enable a subject being tested to blow air into the body; that the body further comprises at least one port for blown air to pass through the port; and that the first end has

a semi-circular cross-sectional profile.

Lutz teaches:

A device for measuring redox gases, such as alcohol, in a person's breath, which comprises a disposable mouthpiece (Abstract of Lutz). The mouthpiece (5 of Lutz) comprises a second end (39 of Lutz) and a first end (27 of Lutz). The second end is closed and rounded to facilitate engagement with the breath testing device (Fig. 1 of Lutz). The mouthpiece has a substantially semi-circular (the cross-section at 27 of Lutz).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have substituted the mouthpiece of the metabolic calorimeter of Mault with a mouthpiece similar to the one taught by Lutz, in order to test the breath gases of a subject. The substitution of one known element in the art with another would have yielded predictable results.

In reference to claim 49:

Mault, as modified by Raemer, teaches all of the claim limitations; see the rejection of claim 47 above.

The body further comprises an external surface (The outside surface of mouthpiece 5 of Lutz), an internal surface (inside surface of mouthpiece 5 of Lutz), and at least one outlet port (39 and 15 of

Lutz) extending there between, where the outlet port channels discard breath air from the mouthpiece during testing.

23. Claim 54-55 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Lutz.

In reference to claims 54-55 and 57-60:

Mault teaches:

A calorimeter for measuring the metabolic rate of a subject which comprises a mouthpiece (20 of Mault). The mouthpiece comprises a first end (seal 354 of Mault), a second end (the end attached to 346 of Mault), and a body extending there between (344 of Mault). A portion of the body has a selected cross-sectional shape being one of a D-shaped cross-sectional shape and a V-shaped cross-sectional shape (Fig. 23 of Mault discloses a D-shape cross-section. The design of the mouthpiece or using an entirely different shape mouthpiece would not change the functionality of the claimed invention. The body further comprises a passageway extending through the body from the first end towards the second end (Fig. 24 of Mault), where the passageway channels the air blown into the mouthpiece into the breath testing device (Fig. 4 of Mault). The port (72 of Mault) is defined within the second body portion for channeling air blown into the first end into



the breath testing device during testing (inlet port 30 of Mault). One of the first end and the second end is rounded to facilitate engagement with the breath testing device (the connection 346 of Mault to the second end of the mouthpiece). One of the first body portion and the second body portion has a substantially semi-circular cross-sectional shape (Fig. 24 of Mault).

The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used a different design for the mouthpiece of Mault such as a mouthpiece with a V-shape cross-section rather than a D-shape cross-section. Applicant has not disclosed that choosing a V-shape cross-section for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs. It would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentably distinguish over the prior art of Mault.

However, Mault fails to teach that:

One port is defined within the first body portion for channeling discard breath air from the mouthpiece during testing, and it is oriented with respect to the mouthpiece such that discard breath is not directed towards an operator of the breath testing device during testing. The second end of the mouthpiece is closed, while the first end is open to enable a subject being tested to blow air into the mouthpiece.

Lutz teaches:

A device for measuring redox gases, such as alcohol, in a person's breath, which comprises a disposable mouthpiece (Abstract of Lutz). The mouthpiece (5 of Lutz) comprises a second end (39 of Lutz) and a first end (27 of Lutz). The second end is closed and rounded to facilitate engagement with the breath testing device (Fig. 1 of Lutz). The mouthpiece has a substantially semi-circular (the cross-section at 27 of Lutz). Lutz also discloses that the exhaled air is passed through an opening (15 of Lutz) in order to be analyzed by the alcohol sensors to detect the blood alcohol levels of the user (Fig. 2 and Col. 3, lines 26-53 of Lutz).

It would have been obvious to one having ordinary skill in the art at time the applicant's invention was made to have substituted the mouthpiece of the metabolic calorimeter of Mault with a mouthpiece similar to the one

taught by Lutz, in order to test the breath gases of a subject. The substitution of one known element in the art with another would have yielded predictable results.

### ***Conclusion***

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner, Art Unit 3735  
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